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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,940	09/09/2003	Jason D. Meridew	5490-000341	1613

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EXAMINER

SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/657,940

Applicant(s)

MERIDEW ET AL.

Examiner

Richard R. Shaffer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-44 is/are pending in the application.
4a) Of the above claim(s) 13-15 and 39 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-12, 16-21, 23-38 and 40-44 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of previous claims 9-12, 22, 23, 26 and 32-34 is withdrawn in additional review of previous art of record as well as the newly discovered reference(s) to Martinek (US Patent 6,840,953). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "the aperture" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 12 is rejected for being dependent upon an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

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351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9-12, 20, 21, 26, 28, 29, and 32-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Greenfield (US Patent 5,584,835).

Greenfield discloses a system comprising: an implant (50) having outer threads; a driver (205) having a cutting portion (207) which forms an implant engaging surface (by threading implant 50) and a driving portion (unseen handle or body portion to allow for easier pressure application); a staple (51) having an upward locking surfaces (55) to engage with internal locking surfaces with in implant (50); and a graft (63) interposed between the staple (51) and implant (50).

Greenfield discloses a method (between **Figures 3, 8, and 9** as well as throughout the specification) comprising: forming an implant engaging surface within a bone aperture while driving an implant (50, 101) into a bone aperture with driver (205); inserting a staple (51, 90) into a slot (100) which is located within the bone aperture when implant (50, 101) is in place, the staple (51, 90) directly engages the implant and indirectly engages the bone aperture; the slot (100) is formed within the bone aperture once implant (50, 101) is driven into place; channels inherently exist in implant (50, 101) due to the disclose (**Column 8, Lines 44-67**) where Greenfield discloses that a counterclockwise rotation will back out the staple (51, 101); the channels are normally engaged by anchor locking members (55); thus when the staple is inserted, it is inserted into the slot (100) as well as the channels; a graft (63) is placed between (**Figure 9**) a graft holding face (53) of the implant (50, 101) and a graft holding surface (58) of the staple (51, 90).

Claims 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohrs et al (US Patent 5,897,593).

Kohrs et al disclose a generally cylindrical implant (**Figure 1**) having a first end (**24**), a second end (**22**), a threaded outer surface, and two channels (**44a**); a staple (**Figure 14**) having a locking surface (**116b**) to engage with the surface (**44**) of the implant. Both the staple and implant include a surface that could hold a graft should it be desired. When inserted, the staple will inhibit rotation of the implant while being positioned within a slot found within bone.

Claims 36-38 and 40-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Martinek (US Patent 6,840,953).

Martinek discloses a method of driving a threaded implant (**14**) comprising: forming a final aperture (**B, Figure 9**) within bone (**A**) while linearly driving/rotating the implant coupled a driver (**12**) simultaneously; and coupling soft tissue (**C**) to the implant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 20, 23-25, 27, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kohrs et al in view of Michelson (US Patent 6,120,503)

Kohrs et al disclose a cylindrical threaded bone screw (**Figure 1**) with two channels (**44a**) extending from a first end (**24**) to a second end (**22**) having an anchor

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locking surface (44); a driver (**Figure 14**) having a threaded cutting portion (114) and a driving portion (112a); wherein the cutting portion is configured to form an implant engaging surface within bone; and wherein the driving portion is configured to drive the implant into engagement with the implant engaging surface. The cutting portion (114) includes a plurality of thread forming portions (118) linearly spaced along the cutting portion. The cutting portions positioned within the channels (44a).

Column 7, Line 55 through Column 8, Line 65 discloses the pertinent surgical method. A method of forming an aperture within a bone; coupling the implant to a driver (**Figure 14**), rotating the implant causing the implant to linearly translate into the aperture while simultaneously having the driver and implant form a threaded implant engaging surface within the aperture. A slot is formed within the bone aperture once the implant has been inserted and the driver removed. The slot formed through the linear translation of the driver.

Kohrs et al disclose all of the claimed limitations except for a fastener (claim 1) or staple (claim 20) fixed to the implant and bone aperture through slots as well as the implant being made of a resorbable material. Michelson teaches (**Column 3, Lines 17-23**) that using resorbable materials are known in the art to allow the body to replace the device over time. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use resorbable materials for the implant to allow the body to replace the implant with natural tissue, which would minimize complications or drawbacks to non-biological components.

Michelson further teaches (**Column 2, Lines 12-50**) that threaded spinal fusion implants often become dislodged and a reliable means for fixation is through the use of a staple (**Figure 9**) with an anchor surface (**34**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a staple according to the teaching of Michelson with the implant of Kohrs et al to improve implantation fixation. The staple is screwed to the threaded implant through a bore running longitudinally through the implant. The staple is inherently inserted into slots (**53a, 53b**) and directly engages the implant and indirectly engages the bone aperture through the implant.

Response to Arguments

Applicant's arguments filed April 19th, 2006 in regard to claims 16-19 have been fully considered but they are not persuasive. In response to applicant's argument that element (**110**) cannot be reasonably interpreted as being a staple; a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant's arguments with respect to claims 1-12, 20, 21, 23-38, and 40-44 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

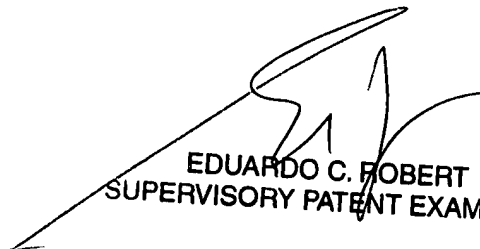
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
June 29th, 2006



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER